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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/004,969 | 12/03/2001 | Stephen Bresina | 2678 | 7840 |
| 530 | 7590 | 08/11/2004 | EXAMINER | |
| LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090 | | | PHILOGENE, PEDRO | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3732 | |

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | | |
|------------------------------|------------------------|--|---------------------|--|
| Office Action Summary | Application No. | | Applicant(s) | |
| | 10/004,969 | | BRESINA, STEPHEN | |
| | Examiner | | Art Unit | |
| | Pedro Philogene | | 3732 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5 and 7-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,7-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/26/04 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 5, 7, 10-12, 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bresina et al. (6,395,035) in view of Williams et al (6,113,638) in view of Lin (6,629,998).

With respect to claim 1, Bresina et al disclose an apparatus for facilitating fusion of adjacent vertebrae, comprising an implant (1) body dimensioned for positioning within an intervertebral space between upper and lower vertebrae to maintain the vertebrae in desired spaced relation to facilitate fusion thereof, the implant body including lower and upper surfaces for engaging respective lower and upper vertebrae, and first and second side wall portions; as best seen in FIGS. 5,6; extending between the upper and lower surfaces, the first and second wall portions being substantially solid, at least one of the

Art Unit: 3732

first and second side wall portions having a substantially narrow longitudinal slit (8) defined therein arranged to enhance flexibility of the side wall portion.

It is noted that Bresina et al did not teach of an implant body including two or more bores extending through the upper and lower surfaces for reception of bone growth inducing substances, the bores in communication with the slit, as claimed by applicant. However, in a similar art, Williams evidences the use of an implant having two or more bores (103) extending through the upper and lower surfaces for reception of bone growth inducing substances, the bores in communication with the channel (105) for receiving bone graft material therein.

Therefore, given the teaching of Williams, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Bresina et al., as taught by Williams, with two or more bores in upper and lower surfaces, in communication with the slit of Bresina et al., to provide a passage for receiving bone growth inducing material therein.

It is noted that the above combination did not teach of bores having intersecting wall portions forming a communication path extending from upper to lower surface; as claimed by applicant. However, in similar art, Lin (FIG.8) evidences the use of bores having intersecting wall portions forming a communication path extending from the upper to the lower surface to secure the implant and promote bone growth.

Therefore, given the teaching of Lin, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Bresina/Williams, as taught by Lin to secure the implant and promote bone growth.

With respect to claims 2,5, 7,10-12, 27, the above combination of references discloses all the limitations, as set forth in columns 4-6, lines 1-67; and as best seen in FIGS. 1-11 of Bresina et al., and as set forth in column 7, lines 33-46; and as best seen in FIG. 5A of Williams.

With respect to claims 14-17, the method steps, as set forth, would have been obviously carried out in the operation of the device, as set forth above.

Claims 20-22,24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heggeness et al (5,514,180) in view of Williams et al. (6,113,638) in view of Lin (6,629,998).

With respect to claim 20, 24, Heggeness et al discloses a kit for fusion of adjacent vertebra comprising a plurality of implants (60,70,80,90,100), each having an implant body including an upper and a lower surfaces for engaging respective adjacent vertebra and sidewall position extending between the upper and lower surfaces and surrounding an internal cavity having plurality of generally cylindrical internal bores open to the upper and lower surfaces; as best seen in Fig.25; a plurality of bone plugs, as set forth in column 11, lines 40-49, sized to fit into each of the cylindrical internal bores.

It is noted that Heggeness et al. did not teach of bores having sides in open communication with adjacent bores, as claimed by applicant. However, in a similar art, Williams et al evidence the use of an implant having at least three bores (103) with sides in open communication with adjacent bores; as best seen in FIG.5A adapted to receive bone growth material.

Therefore, given the teaching of Williams et al., it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Heggeness et al., as taught by Williams to provide an implant with at least three bores in open communication with adjacent bores adapted to provide a passage for receiving bone growth inducing material therein.

It is noted that the above combination did not teach of bores having sides in open communication with adjacent bores continuously from the upper to the lower surface of the implant; as claimed by applicant. However, in similar art, Lin (FIG.8) evidences the use of bores having sides in open communication with adjacent bores continuously from the upper to the lower surface to secure the implant and promote bone growth.

Therefore, given the teaching of Lin, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Heggeness/Williams, as taught by Lin to secure the implant and promote bone growth.

With respect to claims 21-22, Heggeness et al disclose all the limitations, as set forth in column 11, lines 40-49 and as best seen in Fig.25.

Claims 13,18,19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bresina et al (6,395,035) in view of Williams et al. (6,113,638) in view of Lin (6,629,998) in view of Heggeness et al. (5,514,180).

With respect to claims 13,18,19, it is noted that the above combination of references did not teach of a plurality of internal bores, further including bone plug; as claimed by applicant. However, in a similar art, Heggeness et al. (FIG.25) evidences the

Art Unit: 3732

use of an implant with a plurality of internal bores and including bone plug to facilitate bone growth.

Therefore, given the teaching of Heggeness et al., it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the plurality of internal bores filled with bone plug, as taught by Heggeness et al., in the device of Bresina/Williams et al to facilitate bone growth.

Claims 8,9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bresina et al (6,395,035) in view of Williams et al., (6,113,638) in view of Lin (6,629,998) in view of Biscup (6,245,108).

With respect to claims 8,9, it is noted that Bresina the above combination of references did not teach of a plurality of ridges and grooves on the upper and lower surfaces of the implant; as claimed by applicant. However, in a similar art, Biscup evidences the use of an implant with ridges and grooves on top and bottom surfaces to engage the surface of an adjacent vertebra.

Therefore, given the teaching of Biscup, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate ridges and grooves on the upper and lower surfaces of the device of Bresina/Williams et al/Lin to engage the surface of an adjacent vertebra.

Claims 23,25,26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heggeness et al (5,514,180) in view of Williams et al. (6,113,638) in view of Lin (6,629,998) in view of Bresina et al. (6,395,035).

With respect to claim 23,25,26, it is noted that the above combination of references did not teach of an implant body including slit in the sidewall in communication with the bore, as claimed by applicant. However, in a similar art, Bresina et al evidence the use of an implant with a slit in the sidewall in communication with a bore to provide an implant that absorbs stress transfer by the cage to the graft material.

Therefore, given the teaching of Bresina et al., it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Heggeness/Williams et al/Lin., as taught by Bresina et al to provide an implant that absorbs stress transfer by the cage to the graft material.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

6,371,987

04-2002

Weiland et al.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pedro Philogene whose telephone number is (703) 308-2252. The examiner can normally be reached on Monday to Friday 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P Shaver can be reached on (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3732

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pedro Philogene
August 06, 2004


PEDRO PHILOGENE
PRIMARY EXAMINER